DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 12, 2014

Orthofix Srl
% Mr. Troy Brooks
Senior Regulatory Affairs Specialist
3451 Plano Parkway
Lewisville, Texas 75056

Re: K141571
Trade/Device Name: Orthofix Ankle Hindfoot Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: October 10, 2014
Received: October 14, 2014

Dear Mr. Brooks,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141571

Device Name
Orthofix Ankle Hindfoot Nailing System

Indications for Use *(Describe)*
The Orthofix Ankle Hindfoot Nailing System is intended to facilitate tibiotalocalcaneal arthrodesis (fusion). Specific indications include:

1. Avascular necrosis of the talus
2. Failed total ankle arthroplasty
3. Trauma (malunited tibial pilon fracture)
4. Severe deformity or instability as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease
5. Revision ankle arthrodesis
6. Neuroarthropathy
7. Rheumatoid arthritis
8. Osteoarthritis
9. Pseudoarthrosis
10. Post-traumatic arthrosis
11. Previously infected arthrosis
12. Charcot foot
13. Severe endstage degenerative arthritis
14. Severe defects after tumor resection
15. Pantalar arthrodesis

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5.0 510(k) Summary K141571

Date Prepared:	October 10, 2014
Purpose for Submission:	New product offering
Sponsor:	Orthofix Srl Via delle Nazioni 9 37012 Bussolengo (VR) Italy
Contact:	Orthofix Troy Brooks, RAC Tel: 214-937-2047 Fax: 214-937-3322
Trade Name / Proprietary Name:	Orthofix Ankle Hindfoot Nailing System
Common Name:	Intramedullary Nail
Product Code:	HSB - Rod, Fixation, Intramedullary And Accessories
Classification:	Class II – 21 CFR § 888.3020 – Intramedullary Fixation Rod
Predicate Device:	Biomet Phoenix Ankle Arthrodesis Nail System – K091976
Device Description:	The Orthofix Ankle Hindfoot Nailing System comprises a variety of implantable intramedullary nails with respective locking end caps and locking screws manufactured from titanium alloy (Ti6Al4V) which are intended to facilitate tibiotalocalcaneal arthrodesis (fusion). The system also includes instrumentation required for implantation and explantation of the implants.
Intended Use / Indications For Use:	The Orthofix Ankle Hindfoot Nailing System is intended to facilitate tibiotalocalcaneal arthrodesis (fusion). Specific indications include: 1. Avascular necrosis of the talus 2. Failed total ankle arthroplasty 3. Trauma (malunited tibial pilon fracture) 4. Severe deformity or instability as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease 5. Revision ankle arthrodesis 6. Neuroarthropathy 7. Rheumatoid arthritis 8. Osteoarthritis 9. Pseudoarthrosis 10. Post-traumatic arthrosis 11. Previously infected arthrosis 12. Charcot foot 13. Severe endstage degenerative arthritis 14. Severe defects after tumor resection 15. Pantalar arthrodesis
Technological Characteristics Summary:	The technological characteristics of the Orthofix Ankle Hindfoot Nailing System are similar to the predicate device in terms of general design, dimensions, intended use, materials, and performance characteristics.

	The following technological differences exist between the Orthofix Ankle Hindfoot Nailing System and the predicate device: • The intramedullary nails have a distal flare • The intramedullary nails have additional fixation points in some lengths • The intramedullary nails have a smaller inner diameter • The locking screws are also offered in a threaded-head version • The locking screws are also offered in lengths of 115mm and 120mm
Non-Clinical Testing:	Mechanical testing of the Orthofix Ankle Hindfoot Nailing System consisting of Static Four-Point Bend testing, Static Torsion testing, and Bending Fatigue testing was conducted in accordance with ASTM F1264-03 "*Standard Specification and Test Methods for Intramedullary Fixation Devices."* Test results demonstrate that the Orthofix Ankle Hindfoot Nailing System is substantially equivalent to the predicate device.
Substantial Equivalence:	Based upon similarities in design, materials, intended use, indications for use and the results of mechanical testing, the Orthofix Hindfoot Nailing System is substantially equivalent to the predicate device.